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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/682,372	10/10/2003	Stig Olmar	P08079US01/BAS	6095
881 7590 12/10/2008 STITES & HARBISON PLLC 1199 NORTH FAIRFAX STREET SUITE 900 ALEXANDRIA, VA 22314			EXAMINER NATNITHITHADHA, NAVIN	
			ART UNIT 3735	PAPER NUMBER
			MAIL DATE 12/10/2008	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/682,372

**Applicant(s)**

OLLMAR ET AL.

**Examiner**

NAVIN NATNITHADHA

**Art Unit**

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 17 September 2008.  
2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.  
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-17 and 19-43 is/are pending in the application.  
4a) Of the above claim(s) 1-13 is/are withdrawn from consideration.  
5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.  
6) ☒ Claim(s) 14-17 and 19-43 is/are rejected.  
7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.  
8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.  
10) ☒ The drawing(s) filed on 20 August 2007 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)  
2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)  
3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_  
4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_  
5) ☐ Notice of Informal Patent Application  
6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 17 September 2008 has been entered.

### ***Response to Amendment***

2. According to the Amendment, filed 20 August 2007, the status of the claims is as follows:

Claims 14-16, 19, 20, 25, and 28 are currently amended;

Claim 21 are as originally filed;

Claims 17, 22-24, 26, 27, and 29 are previously presented;

Claims 1-13 are withdrawn;

Claims 30-43 are new; and

Claim 18 is cancelled.

***Response to Arguments***

3. Applicant's arguments, see Request for Reconsideration After Final, pp. 1-13, filed 08 August 2008, with respect to the rejection of claims 14-17 and 19-43 under 35 U.S.C. 103(a) as being unpatentable over Davies et al, U.S. Patent No. 6,922,586 B2 ("Davies") in view of Sieburg et al, U.S. Patent No. 7,103,398 B2 ("Sieburg"), have been fully considered, but are moot in view of the new ground(s) of rejection.

***Claim Rejections - 35 USC § 103***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

4. Claims 14-17 and 19-43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Davies in view of Stemme et al, U.S. Patent Application Publication No. 2004/0054393 A1 ("Stemme").

Claims 14-17 and 19-29: As to claims 14-16, 19-21, and 27-29, Davies teaches a method for diagnosing a diseased condition of the skin (see Abstract and figs. 1-4), the method comprising the steps of:

(i) placing an electrical conducting probe ("prove device") 105/400 against a skin surface of the subject (see fig. 4A), wherein the probe 105/400 comprises a plurality of electrodes (see fig. 3), wherein a first electrode ("current passing electrodes") 5 and a second electrode (first ring of "voltage sensing electrodes") 8 of the plurality of electrodes are spaced a first distance from each other and wherein the first electrode 5

and a third electrode (second, inner ring of "voltage sensing electrodes") 8 of said plurality of electrodes are spaced a second distance from each other;

(ii) passing an electrical current through the electrodes to obtain a value of skin impedance, wherein said electrical current is separately passed between the first electrode 5 and the second electrode (first ring of "voltage sensing electrodes") 8 and between the first electrode 5 and the third electrode (second, inner ring of "voltage sensing electrodes") 88 to obtain at least a first value of impedance and at least a second value of impedance (see fig. 3 and col. 11, ll. 36-44, and col. 11, l. 64, to col. 12, l. 12); and

(iii) using reference data to determine whether the impedance value indicates the diseased condition, such as skin cancer (see col. 8, ll. 60-65, col. 9, ll. 48-65, col. 9, l. 66, to col. 10, l. 19, and col. 11, ll. 1-4).

Davies does not teach "each electrode furnished with a number of spikes, the spikes being laterally spaced apart from each other and being of sufficient length to penetrate the stratum corneum" in claim 1, along with the subject matter of claims 17 and 22-26, which directed to the amount and dimensions of the spikes. However, Stemme teaches a "medical electrode... comprises a base that includes an array of micro-dimensioned spikes designed to pierce the outer skin layer, i.e. the stratum corneum and penetrate into the electrically conductive stratum germinativum, thereby to circumvent the high impedance characteristics of the stratum corneum SC" (see para. 28). "The spikes are long enough to reach the stratum germinativum and are

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able to carry an electrical signal" (see para. 12). In addition, Stemme teaches the following (see para. 29):

However, the spikes must not reach the tissue layer below the stratum germinativum containing nerves and blood vessels so as to avoid pain or bleeding of the subject. The thickness of the stratum corneum is approximately 10 to 15  $\mu\text{m}$ . The thickness of the stratum germinativum is about 50 to 100  $\mu\text{m}$ . Thus, spikes that penetrate the skin more than 10-15  $\mu\text{m}$ , but less than about 50-100  $\mu\text{m}$ , produce a pain-free electrode-electrolyte interface at the stratum germinativum and transform the ionic current induced by active cells into an electronic current. To achieve this, experiments have shown that the spike length of a majority of the spikes in the array should be in the range of 150 to 350  $\mu\text{m}$ , possibly as long as 500  $\mu\text{m}$ .

Therefore, it would have been obvious for one of ordinary skill in the art at the time the invention was made to modify Davies' electrode structure with Stemme's electrode structure because Davies suggests the following:

Alternatively, surface electrodes that just penetrate the stratum corneum may be used to decrease impedance. See col. 10, ll. 58-59.

In one embodiment, electrophysiological measurements are performed using a series of two or more electrodes attached to an examining glove or probe. Some factors influencing the spacing of the electrode and the signal used include the depth of penetration desired and permeabilization of the surface epithelium using penetrating agents. A probe that permits variable frequency signals and varying electrode placement provides the most versatile arrangement, but a probe or glove providing a single frequency signal and/or static electrode placement may also be used. See col. 13, ll. 55-65.

Applicant's arguments, in regard to the Davies' combinability to electrode structures that can penetrate the stratum corneum, see Request for Reconsideration After Final, p. 4, filed 08 August 2008, is not persuasive because of the explicit suggestion above by Davies.

Claims 30-43: Because Applicant stated that the added new apparatus claims 30-43 correspond to method claims 14-17, 19-27, and 29, respectively, and are not independent and distinct inventions, the claims 30-43 are rejected for the same reasons as stated above for claims 14-17, 19-27, and 29.

### ***Conclusion***

5. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

The other patents cited in the PTO-892 teach subject matter related to the Applicant's claims. The Examiner suggests reviewing these patents before responding to the present Office Action.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to NAVIN NATNITHITHADHA whose telephone number is (571)272-4732. The examiner can normally be reached on Monday-Friday, 9:00 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor, II can be reached on (571) 272-4730. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Navin Natnithithadha/  
Patent Examiner, Art Unit 3735  
12/08/2008